In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: November 30, 2023

BRETT VAN LEER-GREENBERG, *as father and natural guardian of H.V.L., a minor,*	*	No. 20-1150V
Petitioner,	*	Special Master Sanders
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Michael A. London, Douglas & London, P.C., New York, NY, for Petitioner.
Lauren Kells, U.S. Department of Justice, Washington, DC, for Respondent.

DECISION ON ENTITLEMENT[1]

On September 4, 2020, Brett Van Leer-Greenberg ("Petitioner") filed a petition pursuant to the National Vaccine Injury Compensation Program.[2] Petitioner alleged that his child, H.V.L., "suffered a Table [i]njury, specifically thrombocytopenic purpura[3][]" after receiving the measles,

[1]Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755 ("the Vaccine Act" or "Act"). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

[3] Thrombocytopenic purpura is "any form of purpura in which the platelet count is decreased[.]" *Dorland's Illustrated Medical Dictionary* 1534 (33rd ed. 2020) [hereinafter "*Dorland's*"]. Platelets are "disk-shaped structure[s] . . . found in the blood of all mammals and chiefly known for [their] role in blood coagulation[.]" *Id.* at 1437. Purpura is "any of a group of conditions characterized by ecchymoses or other small hemorrhages in the skin, mucous membranes, or serosal surfaces; causes include blood disorders, vascular abnormalities, and trauma." *Id.* at 1533. It also refers to "any of several conditions similar to the traditional purpura group, which may be caused by decreased platelet counts, platelet

mumps, rubella ("MMR") vaccine on September 10, 2018. Pet. at 1, ECF No. 1. Alternatively, Petitioner alleged that H.V.L. suffered from thrombocytopenic purpura that was caused-in-fact by the MMR, hepatitis A, and varicella vaccines he received on September 10, 2018. *Id.* After carefully analyzing and weighing all the evidence and testimony presented in this case in accordance with the applicable legal standards,[4] I find that Petitioner has not provided preponderant evidence that H.V.L.'s injury lasted for six months pursuant to the Vaccine Act's severity requirement. Accordingly, Petitioner is not entitled to compensation.

I. Procedural History

Petitioner filed his petition on September 4, 2020. Pet. He filed medical records on September 10, 2020, and an affidavit;[5] a letter from Rebecca Farber, M.D., H.V.L.'s pediatrician; and a statement of completion on September 18, 2020. Pet'r's Exs. 1–5, ECF No. 6; Pet'r's Exs. 6, 8, ECF No. 7; ECF No. 8.

On December 16, 2020, Respondent contacted Chambers via email and indicated that he required additional medical records from Petitioner to formulate his position in this case. Informal Comm., docketed Dec. 22, 2020; Scheduling Order at 1, ECF No. 13. I ordered Petitioner to file the additional records requested and a "status report citing to the medical records that support the six-month severity requirement[]" by January 21, 2021. Scheduling Order at 1. Petitioner filed the additional medical records and his status report on January 18, 2021. Pet'r's Ex. 9, ECF No. 14-1; ECF No. 15.

On August 30, 2021, Respondent filed his Rule 4(c) report and argued that "[P]etitioner cannot satisfy the six month requirement under the Act[,] and his claim must fail." Resp't's Report at 10, ECF No. 19. On October 27, 2021, I ordered Petitioner to file any outstanding laboratory results from H.V.L.'s birth to the present as well as sworn affidavits or other documentation from two of his treating physicians. Scheduling Order at 1–2, ECF No. 20. Petitioner filed a letter from Shipra Kaicker, M.D., on March 24, 2022. Pet'r's Ex. 10, ECF No. 26-1. He filed a letter from Dr. Farber on July 12, 2022. Pet'r's Ex. 11, ECF No. 32-1. Also on July 12, 2022, Petitioner filed a status report stating that he had filed all of the laboratory results. ECF No. 33 at 1–3.

On August 15, 2022, Respondent filed a status report stating that he "continues to contest the six-month severity requirement in this case and recommends that the Court resolve entitlement

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abnormalities, vascular defects, or reactions to drugs." *Id.* An ecchymosis is "a small hemorrhagic spot[] . . . in the skin or mucous membrane forming a nonelevated, rounded or irregular, blue or purplish patch." *Id.* at 582.

[4] While I have reviewed all of the information filed in this case, only those filings and records that are most relevant to the decision will be discussed. *Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision.") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.*, 527 F. App'x 875, 884 (Fed. Cir. 2013) ("Finding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered.").

[5] Petitioner's affidavit is brief and does not address the duration of H.V.L.'s injury. *See* Pet'r's Ex. 6, ECF No. 7-1.

on the record." ECF No. 35 at 2. On August 18, 2022, I ordered Petitioner "to identify (through a status report with cites to the record) and/or file any evidence supporting the fact that H.V.L. was suffering from a manifestation of his immune thrombocytopenic purpura ("ITP")[6] between his platelet testing in February and April 2019[.]" Scheduling Order at 2, ECF No. 36. I also ordered Respondent to file "any evidence in support of his position that a platelet count of 149,000 would not be diagnosed as ITP by a medical provider." *Id.* On September 26, 2022, Respondent filed medical literature and a status report. Resp't's Exs. A–E, ECF No. 39; ECF No. 40. Petitioner followed with a status report on September 27, 2022. ECF No. 41.

This matter is now ripe for consideration.

II. Summary of Relevant Evidence

a. Medical Records

H.V.L. was born on September 5, 2017. *E.g.*, Pet'r's Ex. 2 at 67, ECF No. 6-2. He received the vaccinations at issue on September 10, 2018, during his twelve-month appointment with his pediatrician, Dr. Farber. *Id.* at 67–68; Pet'r's Ex. 1 at 1, ECF No. 6-1. On October 1, 2018, H.V.L. returned to Dr. Farber, and his parents reported "worsening bruising over [the] past few days." Pet'r's Ex. 2 at 71. His parents reported that H.V.L. "developed [a] fever within a few days of the vaccines" and developed a "small red rash at the [ten] day mark that ha[d] since faded." *Id.* Although the rash had faded, H.V.L.'s parents "noted more bruising over the weekend, even on his bottom and face and back." *Id.* On exam, H.V.L. had petechiae in the posterior palate and bruising on the forehead, back, hand, legs, and bottom. *Id.* at 72. Dr. Farber's assessment included thrombocytopenia and "easy bruisability[.]" *Id.* She noted "presumed ITP = post viral or post immunization[]" and "possibly triggered by virus vs. MMR vaccine." *Id.* Dr. Farber directed H.V.L.'s parents to take him to the emergency room ("ER"). *Id.*

H.V.L. presented to the ER on October 1, 2018, and the chief complaint was low platelets, as well as rash and petechiae. Pet'r's Ex. 9 at 15. H.V.L.'s parents reported that he received a set of vaccines, including MMR, on September 10, and that he "had [a] fever for [five] days afterwards with diffuse rash along [his] body" that had improved. *Id.* On exam, H.V.L. had diffuse petechiae and ecchymosis but no active bleeding. *Id.* at 17. H.V.L.'s platelet count was 7,000, and he was diagnosed with ITP. *Id.* at 1, 17. H.V.L. was admitted to the hospital. *Id.*

After admission, H.V.L. was evaluated by a pediatric hematologist-oncologist, Catherine McGuinn, M.D. *Id.* at 23. Dr. McGuinn's assessment was "[one] year old with presumed ITP based on review of laboratory finding, physical exam and clinical history with temporal relationship to MMR vaccine, which is a reported risk factor for [approximately six] weeks post immunization." *Id.* She reviewed with H.V.L.'s parents "the working diagnosis of ITP given [the] short timeframe

[6] ITP, or idiopathic purpura, is "a type of thrombocytopenic purpura that is not directly associated with any definable systemic disease but often follows a systemic infection; it has been found to be an autoimmune condition, caused by antigens against platelets, resulting in ecchymoses, petechiae, and other bleeding." *Dorland's* at 1533. Petechiae are "pinpoint, nonraised, perfectly round, purplish red spot[s] caused by intradermal or submucous hemorrhage." *Id.* at 1401.

and lack of associated symptoms and stable [hemoglobin ("Hbg")[7] and white blood cell ("WBC")[8]] count/differential." *Id.* She prescribed intravenous immunoglobulin[9] ("IVIG") treatment and repeat complete blood count ("CBC") testing six to eight hours following his IVIG infusion. *Id.* at 24. On October 2, 2018, H.V.L. was noted to have "presumed ITP [status post] MMR vaccination and febrile illness . . . ." *Id.* at 28. H.V.L. received an IVIG infusion, and his platelet count improved to 18,000. *Id.* at 29, 32. H.V.L. was discharged from the hospital on October 3, 2018, "[g]iven [the] lack of ongoing bleeding symptoms[.]" *Id.* at 37. Dr. McGuinn noted that H.V.L.'s "[p]latelet count remain[ed] low" at 18,000 "but [was] rising[,]" and she recommended "close outpatient follow up." *Id.*

On October 5, 2018, H.V.L. presented to Dr. Kaicker, a pediatric hematologist-oncologist. Pet'r's Ex. 4 at 20, ECF No. 6-4. Dr. Kaicker noted that H.V.L. had "new onset immune thrombocytopenia[10] that developed acutely in the context of having received the MMR vaccine[.]" *Id.* H.V.L.'s parents reported that he "developed several bouts of emesis but no fever[]" one day after his hospital discharge but that the vomiting had resolved. *Id.* On exam, Dr. Kaicker noted "[p]urpura and rash[]" and "[r]esolving petechiae and bruises[.]" *Id.* at 21. Dr. Kaicker wrote that H.V.L.'s platelets had increased to 83,000 "[four] days post IVIG[] with resolving symptoms." *Id.* She continued that "[g]iven [H.V.L.'s] age, acute onset of symptoms[,] and possible association with the MMR vaccine, [she] expect[ed] an excellent outcome." *Id.* Dr. Kaicker emphasized the importance of weekly monitoring of H.V.L.'s platelets "as the IVIG effect wears off." *Id.* Dr. Kaicker directed H.V.L.'s parents that H.V.L. should avoid nonsteroidal anti-inflammatory drugs ("NSAIDS"),[11] head trauma, and "additional vaccines at this time[.]" *Id.*

H.V.L. followed up with Dr. Kaicker on October 11, 2018. *Id.* at 14. H.V.L.'s parents "denie[d] all bleeding symptoms[]" and noted "[n]o new bruises or petechiae." *Id.* They reported that "[p]rior bruises resolved by Friday and over the course of the past week have fully resolved." *Id.* H.V.L.'s platelet count was 53,000. *Id.* at 15–16. He returned to Dr. Kaicker on October 16, 2018, and his mother noted new petechiae on his left arm but "[n]o other bruising or bleeding symptoms." *Id.* at 10–11. However, his mother reported "[t]ransient bruising from play and falling[.]" *Id.* at 11. On exam, Dr. Kaicker noted "[f]ading bruises[and o]ccassional petechiae over arm[.]" *Id.* Dr. Kaicker's assessment remained "[n]ew onset ITP post MMR[.]" *Id.* She noted a decline in H.V.L.'s platelets, which dropped to 28,000. *Id.* at 12. However, she noted that "[g]iven minimal symptoms and no wet purpura[, she] recommend[ed] continued watchful waiting and monitoring and treating again only when necessary and based on symptoms." *Id.* She provided the following "[a]nticipatory guidance[:]"

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[7] Hemoglobin is "the red oxygen-carrying pigment of erythrocytes, formed by developing erythrocytes in bone marrow." *Dorland's* at 829.

[8] White blood cells, or leukocytes, are "colorless blood cell[s] capable of ameboid movement." *Dorland's* at 1015.

[9] Immunoglobulin is "any of the structurally related glycoproteins that function as antibodies[.]" *Dorland's* at 908.

[10] Thrombocytopenia is a "decreased in the number of platelets, such as in thrombocytopenic purpura." *Dorland's* at 1892.

[11] NSAIDS are "any of a large, chemically heterogeneous group of drugs that inhibit cyclooxygenase activity, resulting in decreased synthesis of prostaglandin and thromboxane precursors from arachidonic acid." *Dorland's* at 562.

(1) No Aspirin or NSAIDS
(2) No [intramuscular] injections
(3) Limit rough play
(4) Hold MMR or MMRV vaccination for at least [ten] months post IVIG . . .
(5) Call or seek medical attention for new wet purpura: Prolonged epistaxis, oral bleeding, blood in urine or stool

Id. On October 25, 2018, H.V.L. returned to Dr. Kaicker with "[v]ery minimal petechiae/purpura [ ]." *Id.* at 6. On exam, H.V.L. had "[m]inimal small fading bruises[.]" *Id.* at 7. H.V.L.'s platelet count was 52,000, and Dr. Kaicker noted that his "[p]latelet counts [were] trending upwards again after a transient drop again post IVIG." *Id.* She directed "[c]ontinue[d] monitoring and watchful waiting[.]" *Id.*

H.V.L.'s continuing platelet testing showed counts of 45,000 on November 5, 2018, 62,000 on November 14, 2018, and 79,000 on November 26, 2018. Pet'r's Ex. 3 at 42–43, ECF No. 6-3. He presented to Dr. Farber for his fifteen-month, well-child visit on December 10, 2018, and an exam revealed a bruise on his back. Pet'r's Ex. 2 at 76–77. Dr. Farber noted, "[v]accination not done because of acute illness[,]" and she noted that H.V.L. was "recovering from ITP." *Id.* at 78. She noted that H.V.L. would receive his "15 mo[nth] Pentacel, prevnar" vaccines "[w]hen [he] returns to NYC." *Id.* His CBC on the same day revealed a platelet count of 94,000. Pet'r's Ex. 3 at 44. H.V.L. returned to Dr. Farber for a vaccine visit on January 2, 2019, and Dr. Farber noted that he was "cleared for inactivated non-live vaccines[.]" *Id.* at 80. H.V.L. received Pentacel and Prevnar vaccines. *Id.* at 81. On exam, H.V.L. had "no rash[,]" and Dr. Farber did not note any bruises. *Id.* H.V.L. had a platelet count of 118,000 on January 3, 2019. Pet'r's Ex. 3 at 47.

On February 4, 2019, a CBC revealed that H.V.L. had a platelet count of 149,000. Pet'r's Ex. 3 at 48. H.V.L. returned to Dr. Farber after falling and suffering a buccal laceration on February 28, 2019. Pet'r's Ex. 2 at 84. H.V.L.'s parents reported that he "fell and likely bit inside of mouth[.]" *Id.* They told Dr. Farber that they "saw a great deal of blood, but bleeding stopped quickly- within [five minutes]." *Id.* H.V.L.'s parents reported that his "recent platelet count [was] close to 200,000.[12]" *Id.* On exam, H.V.L. had an ulceration/laceration on his inner left cheek and a bruise on his left cheek. *Id.* at 85. Regarding H.V.L.'s ITP, Dr. Farber wrote, "improving, last level. obs. no other bruising/bleeding." *Id.*

On March 11, 2019, H.V.L. presented to Dr. Farber for his eighteen-month well visit. *Id.* at 88. His parents indicated that he had recently spent one day in the PICU for croup,[13] and they reported that his "last platelets [were] okay.[14]" *Id.* On exam, H.V.L. had a bruise on his left cheek. *Id.* at 89. Dr. Farber no longer listed ITP as in the "dx & clinical assessment" portion of the record. *See id.* at 90. She noted a "hold on immunizations due to current illness[,]" but it is unclear whether this refers to H.V.L.'s croup. *See id.* H.V.L. returned to Dr. Farber for a hepatitis A vaccine on

[12] It is unclear whether H.V.L.'s parents were referring to his February 4, 2019 platelet count. The filed medical records do not indicate any further platelet testing in February of 2019.
[13] The filed medical records include a "pediatric resident admission note" dated March 10, 2019, but they do not appear to otherwise include records from this hospitalization. *See* Pet'r's Ex. 3 at 30–31.
[14] It is again unclear whether H.V.L.'s parents were referring to his February 4, 2019 platelet count.

March 25, 2019. *Id.* at 93–94. Petitioner did not file records indicating that H.V.L. had a CBC in March of 2019.

On April 1, 2019, H.V.L.'s platelet count was 150,000. Pet'r's Ex. 3 at 50. He returned to a different physician in Dr. Farber's office on April 20, 2019, for an upper respiratory infection. Pet'r's Ex. 2 at 97. His physical exam revealed congestion but was otherwise normal. *See id.* at 98.

On August 31, 2020, Petitioner spoke with a nurse practitioner at Dr. Kaicker's office to request a letter to present to his lawyer regarding "the time course of [H.V.L.'s] illness." Pet'r's Ex. 9 at 39. Following the call, Petitioner emailed the nurse practitioner and included a sample letter. *Id.* at 39–40. Petitioner asked the nurse practitioner to "please review [the sample letter] and let [him] know if any changes or additions are necessary for Dr. K[aicker]." *Id.* at 39. In the sample letter, Petitioner[15] wrote that H.V.L. "required serial laboratory testing, in order to monitor platelet levels at regular intervals, to follow their trend until his platelet count was objectively normal." *Id.* at 40. Petitioner continued that "[d]uring this interval [H.V.L.] was maintained on restricted physical activity and were [sic] not lifted until his platelets had objectively normalized after April 1st 2020." *Id.* He further wrote that "[t]he April 1, 2020 testing was necessary because, prior to then, [H.V.L.'s] ITP had not resolved. The platelet tests were ordered in response to the fact that his platelet counts had not resolved and we, as his physicians, desired that his platelets normalize." *Id.*

b. Physician Letters

On September 18, 2020, Petitioner filed an undated letter from Dr. Farber. Pet'r's Ex. 8 at 1, ECF No. 7-3. Dr. Farber wrote that H.V.L. "received a diagnosis of MMR vaccine-induced" ITP during his October 2018 hospital admission. *Id.* She continued that "[g]iven his diagnosis of ITP, repeat platelet tests were ordered because it was necessary to determine when his condition would resolve." *Id.* She explained that "[u]ntil his condition resolved and his platelet counts were objectively normal, [she] placed [H.V.L.] on restricted physical activity." *Id.* Dr. Farber noted that "[t]hese restrictions were not lifted until April 1, 2020, [sic] which is the first date on which his platelet levels returned to normal." *Id.* She explained that "[p]rior to this, his condition had not resolved because his platelet counts were below normal." *Id.* Dr. Farber continued that "platelet testing was necessary up through and until April 1, 2020 [sic] because [H.V.L.'s] blood platelet count was below normal up until that time." *Id.* She noted that H.V.L.'s "platelet tests were serially ordered and actively monitored in response to the fact that his platelet counts had not resolved." *Id.* Dr. Farber noted her "desire to ensure that [H.V.L.'s] platelets stabilize[d] prior to resuming normal physical activity." *Id.* On July 12, 2022, Petitioner filed a second letter from Dr. Farber, dated July 11, 2022, in which Dr. Farber explained that her previous letter incorrectly referred to April 1, 2020, rather than to April 1, 2019. Pet'r's Ex. 11 at 1. Dr. Farber wrote that H.V.L.'s "platelets improved to reach the low end of normal at 150,000 (after treatment of IVIG) by April 1, 2019." *Id.*

On March 24, 2022, Petitioner filed a letter from Dr. Kaicker, dated September 24, 2020. Pet'r's Ex. 10 at 1. Dr. Kaicker recounted H.V.L.'s hospitalization and the progression of his

[15] It is unclear whether this sample letter was written by Petitioner or by Petitioner's counsel.

symptoms and treatment. *See id.* She noted that H.V.L.'s platelets rose to "83,000 by day [four] post IVIG treatment[]" but that his platelets "declined again to a nadir of 28,000" fourteen days post IVIG treatment. *Id.* She wrote that "[w]ith the family in agreement, we continued to observe without additional treatment, following the count with serial blood count assessments." *Id.* She continued that H.V.L.'s "platelet count ultimately began to rise without additional therapy by [twenty-three] days after the dose of IVIG and normalized to 150,000 approximately [six] months after his initial diagnosis on" April 1, 2019. *Id.*

c. Medical Literature

Respondent filed five pieces of medical literature in support of his contention that H.V.L.'s injury does not fulfill the Vaccine Act's severity requirement. He filed a 2009 article by Rodeghiero et al.,[16] who noted that "[d]iagnosis and management of [ITP] remain largely dependent on clinical expertise and observation more than on evidence derived from clinical trials of high scientific quality." Resp't's Ex. A at 1, ECF No. 39-1. They continued that "a lack of consensus on standardized critical definitions, outcome criteria, and terminology[]" is "[o]ne major obstacle to the implementation of" such clinical trials. *Id.* To address these issues in evaluating ITP, "an International Working Group (IWG) of recognized experts" convened in October of 2007 and proposed certain criteria and definitions. *Id.* The expert panel determined "[a] platelet count [of] less than 100 x 10^9/L . . . as the threshold for diagnosis." *Id.* at 2. Rodeghiero et al. explained that "[t]his threshold was preferred to the more commonly used level of less than 150 x 10^9/L, based upon a prospective cohort of otherwise healthy subjects with a platelet count between 100 and 150 x 10^9/L, showing that the [ten]-year probability of developing more severe thrombocytopenia (persistent platelet count below 100 x 10^9/L) is only 6.9% [ ]." *Id.* (internal citations omitted). Rodeghiero et al. continued that "in some non-Western populations, platelet count values between 100 and 150 x 10^9/L are frequently found in apparently healthy people." *Id.* (internal citations omitted).[17] Likewise, when defining treatment responses, the panel determined that a platelet count of at least 100 x 10^9/L is defined as a "complete response." *Id.* at 4. Respondent also filed a 2016 paper by Nomura,[18] who noted that "the platelet count is not the sole diagnostic criterion[]" for ITP but that "[a] platelet count in peripheral blood of <100 x 10^9/L is the most important criterion . . . ." Resp't's Ex. B at 1, ECF No. 39-2. Likewise, in 2021, Cooper at al.[19] defined "[p]rimary [ITP as] an autoimmune disorder characterized by reduced platelet counts (< 100 x 10^9/L) and increased bleeding risk in the absence of another cause or disorder associated with thrombocytopenia." Resp't's Ex. C at 2, ECF No. 39-3.

[16] Francensco Rodeghiero et al., *Standardization of terminology, definitions and outcome criteria in immune thrombocytopenic purpura of adults and children: report from an international working group*, 13(11) BLOOD 2386 (2009).
[17] Respondent did not file the cited studies in this case.
[18] Shosaku Nomura, *Advances in Diagnosis and Treatments for Immune Thrombocytopenia*, 9 CLINICAL MEDICINE INSIGHTS: BLOOD DISORDERS 15 (2016).
[19] Nichola Cooper et al., *Immune thrombocytopenia (ITP) World Impact Survey (I-WISh): Impact of ITP on health-related quality of life*, 96 AM. J. HEMATOLOGY 199 (2021).

Respondent also submitted two papers published prior to the IWG's recommendations. He filed a paper by George et al.,[20] published in 1996, that summarized the recommendations of an expert panel regarding diagnosis and treatment of ITP. Resp't's Ex. D, ECF No. 39-4. George et al. did not identify a specific platelet threshold for ITP diagnosis. *See id.* Instead, they wrote that "[b]ecause ITP is defined by low platelet count without another apparent cause, the clinician must know the normal values for the laboratory." *Id.* at 7. Regarding diagnosis of ITP in children, they noted that diagnosis "is based principally on the history, physical examination, [CBC], and examination of the peripheral smear, which should exclude other causes of thrombocytopenia." *Id.* at 1. They further stated that "[c]hildren with platelet counts >30,000 should not be hospitalized and do not routinely require treatment if they are asymptomatic or have only minor purpura[.]" *Id.* Respondent also filed a 2003 study by Kühne et al.,[21] who defined acute ITP as "a duration of thrombocytopenia (<150 x 10^9/L) of [less than six] months." Resp't's Ex. E at 1, ECF No. 39-5.

III. Applicable Legal Standard

The Vaccine Act provides petitioners with two avenues to receive compensation for their injuries resulting from vaccines or their administration. First, a petitioner may demonstrate that she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the provided time period. § 300aa-11(c)(1)(C)(i). The Vaccine Injury Table lists thrombocytopenic purpura as a compensable injury if it occurs within seven to thirty days after administration of a rubella-containing vaccine, including the MMR vaccine. § 300aa-14(a) as amended by 42 CFR § 100.3. To establish that she suffered a Table injury of thrombocytopenic purpura, a petitioner must show that her injury is consistent with the Table's qualifications and aids to interpretation ("QAIs") for thrombocytopenic purpura. *See* 42 C.F.R. § 100.3(c). The QAIs state that thrombocytopenic purpura "is defined by the presence of clinical manifestations, such as petechiae, significant bruising, or spontaneous bleeding, and by a serum platelet count less than 50,000/mm^3." 42 C.F.R. § 100.3(c)(7). Alternatively, a petitioner may receive compensation by demonstrating that she suffered an "off-Table injury," one not listed on the Table, as a result of his receiving a covered vaccine. *See* 42 U.S.C. § 300aa-11(c)(1)(C); *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1319–20 (Fed. Cir. 2006).

Under either method, however, a petitioner must also show that the injured person

> (i) suffered the residual effects or complications of his illness, disability, injury, or condition for more than six months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention[.]

[20] James N. George et al., *Idiopathic Thrombocytopenic Purpura: A Practice Guideline Developed by Explicit Methods for The American Society of Hematology*, 88(1) BLOOD 3 (1996).
[21] Thomas Kühne et al., *A Prospective Comparative Study of 2540 Infants and Children with Newly Diagnosed Idiopathic Thrombocytopenic Purpura (ITP) from the Intercontinental Childhood ITP Study Group*, 143 J. PEDIATRICS 605 (2003).

§ 300aa–11(c)(1)(D)(i)–(iii). Cases may appropriately be dismissed for failure to substantiate the severity requirement. *See, e.g.*, *Hinnefeld v. Sec'y of Health & Human Servs.*, No. 11-328V, 2012 WL 1608839, at *4–5 (Fed. Cl. Spec. Mstr. Mar. 30, 2012) (dismissing case where medical history revealed that petitioner's Guillain–Barré Syndrome resolved less than two months after onset). Petitioner has not alleged, and the record does not support, that H.V.L. suffered an injury resulting in inpatient hospitalization and surgical intervention or that he died as a result of his vaccinations. Thus, Petitioner must establish that H.V.L. "suffered the residual effects or complications of his illness, disability, injury, or condition for more than six months after the administration of the vaccine[.]" *See* § 300aa–11(c)(1)(D)(i).

It is Petitioner's burden to prove his case, including the six-month requirement, by a preponderance of the evidence. *See* § 300aa–13(a)(1)(A). To satisfy the six-month requirement, "[a] potential petitioner must do something more than merely submit a petition and an affidavit parroting the words of the statute." *Faup v. Sec'y of Health & Hum. Servs.*, No. 12-87V, 2015 WL 443802, at *3 (Fed. Cl. Spec. Mstr. Jan. 13, 2015) (quoting *Black v. Sec'y of Health & Hum. Servs.*, 33 Fed. Cl. 546, 550 (1995), *aff'd*, 93 F.3d 784, 792 (Fed. Cir. 1996)). A petitioner cannot establish the length or ongoing nature of an injury merely through his or her own statements, but rather is required to "submit supporting documentation which reasonably demonstrates that the alleged injury or its sequelae lasted more than six months . . . ." *Black*, 33 Fed. Cl. at 550 (internal quotations omitted); *see also Lett v. Sec'y of Health & Human Servs.*, 39 Fed. Cl. 259, 260–61 (1997) ("Section 300–aa13(a)(1) provides that a special master may not award compensation 'based on the claims of [a] petitioner alone, unsubstantiated by medical records or by medical opinion'").

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1280 (Fed. Cir. 2005)). Indeed, when reviewing the record, a special master must consider the opinions of treating physicians. *Id.* In addition, "[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). While a special master must consider these opinions and records, they are not "binding on the special master or court." § 300aa-13(b)(1); *see also Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1346–49 (Fed. Cir. 2010) (affirming the special master's finding that the petitioner suffered from one disease even though the petitioner's treating doctor had diagnosed the petitioner with a different disease). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record . . . ." § 300aa-13(b)(1).

The Federal Circuit addressed the six-month severity requirement and ITP in *Wright v. Sec'y of Health & Hum. Servs.*, 22 F.4th 999 (Fed. Cir. 2022). The Federal Circuit held that a petitioner failed to satisfy the six-month requirement when her child, B.W.'s, platelet count normalized less than three months post ITP onset because his "relatively non-invasive ongoing [platelet] monitoring" was not a "residual effect" pursuant to § 300aa–11(c)(1)(D)(i). *Id.* at 1001, 1003, 1006–07. The Circuit noted that the child experienced later bruising that was not related to

his vaccine injury and that his ongoing testing "did not reveal, constitute, or cause any somatic change[.]" *Id.* at 1001. Defining the language in § 300aa–11(c)(1)(D)(i), the Federal Circuit determined that "[t]he term 'residual effects[]' . . . requires a change within the patient that is caused by the vaccine injury." *Id.* at 1004. It continued that "'[r]esidual' suggests something remaining or left behind from a vaccine injury . . . Because vaccine injuries are somatic conditions defined by their signs and symptoms within the patient, . . . their residues are similarly defined." *Id.* at 1005–06. The Federal Circuit stated that the use of the words "suffered" and "complication" in association with "residual effects" in § 300aa–11(c)(1)(D)(i) "suggest[s] that Congress contemplated residual effects to be detrimental conditions within the patient, such as lingering or recurring signs and symptoms." *Id.* at 1006. It concluded that "[r]ead together, 'residual effects' and 'complications' appear to both refer to conditions within the patient, with 'residual effects' focused on lingering signs, symptoms, or sequelae characteristic of the court of the original vaccine injury, and 'complications' encompassing conditions that may not be 'essential part[s] of the disease' or may be outside the ordinary progression of the vaccine injury." *Id.* at 1006.

In *Wright,* the Federal Circuit noted that "it is sufficient that the vaccine injury be both a but-for cause of the residual effect and a substantial factor in bringing about the residual effect, even if it is not the predominant factor." *Id.* at 1005 (citing *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)). However, it noted that "even if legally caused by his thrombocytopenic purpura, [the child's] testing was not a 'residual effect[.]'" *Id.* at 1005. This is because the "[t]he tests revealed [that the child] had no lingering symptoms or recurrence of thrombocytopenic purpura[;]" and because "there [was] no showing or argument that [the testing] was detrimental to B.W.'s health such that it might qualify under § 300aa–11(c)(1)(D)(i) as a 'residual effect' or a 'complication' of thrombocytopenic purpura." *Id.* at 1006. The Federal Circuit concluded that the ongoing monitoring was "neither an 'ongoing disability' nor indicative that he 'suffered' or was 'seriously injured' within Congress's intended meaning of the severity requirement." *Id.* at 1007 (internal citations omitted).

The Federal Circuit clarified that its decision "do[es] not disturb existing case law holding that a course of treatment lasting longer than six months can be a 'residual effect.'" *Id.* The Circuit cited *H.S. v. Sec'y of Health & Hum. Servs.*, No. 14-1057V, 2015 WL 1588366 (Fed. Cl. Spec. Mstr. Mar. 13, 2015), in which the special master determined that restrictions on physical activity, including restrictions from participating in gym class, recess, and sports, following a skull fracture constituted a "residual effect" because the restriction was medically necessary to prevent aggravation of H.S.'s injury. *Id.*; *H.S.*, 2015 WL 1588366, at *3. The Circuit also cited *Faup*, wherein the special master held that the petitioner fulfilled the six-month requirement because her child needed medication for her arthritis for more than six months. *Wright*, 22 F.4th at 1007; *Faup*, 2015 WL 443802, at *4. The Federal Circuit noted that "[d]uring a long course of treatment, the patient generally has some lingering condition such that symptoms will likely recur if the treatment were stopped. Otherwise, the long course of treatment would not be necessary." *Wright*, 22 F.4th at 1007. The Circuit also clarified that *Wright* "do[es] not decide [ ] whether a course of testing or monitoring that is part of the management or treatment of a condition, necessary even in the absence of possible symptoms, could be a 'residual effect.'" *Id.*

IV. Arguments of the Parties

In support of his claim that H.V.L.'s injury lasted for at least six months, Petitioner notes H.V.L.'s February 4, 2019 platelet count of 149,000, his April 1, 2019 platelet count of 150,000, and Dr. Farber's statement that his condition did not resolve prior to April 1, 2019. ECF No. 15 at 2. Petitioner "confirmed that all laboratory results ha[ve] been filed." ECF No. 33 at 3. However, H.V.L.'s February 17, 2019 medical record indicated that H.V.L. had a recent platelet count of close to 200,000. Pet'r's Ex. 2 at 84. Petitioner argues that this notation "is clearly an error[,] as the laboratory results do not support that H.V.L.'s platelet count was close to 200,000 and no laboratory results exist that support such a result." ECF No. 33 at 3. In response to my order "afford[ing] Petitioner an opportunity to provide evidence showing that H.V.L. was suffering from a manifestation of his ITP between his platelet count on February 4, 2019, and his lab testing on April 1, 2019[,]" Petitioner states that he "is currently unaware of any additional documents, other than the ones already filed, that exist to support the six-month severity requirement." Order at 1, ECF No. 36; ECF No. 41 at 1. Petitioner argues that "[t]he medical records and other documents that have been presented to date are in accord with the U.S. Court of Appeals for the Federal Circuit's opinion in *Wright* . . . and support that the residual effects of [H.V.L.'s] injury lasted for more than six months after the administration of the vaccine at issue." ECF No. 41 at 1.

Contesting that H.V.L.'s injury fulfills the Vaccine Act's severity requirement, Respondent asserts that on February 4, 2019, less than five months post vaccinations, H.V.L.'s "platelet count was 149,000—barely below the medically recognized normal range of 150,000 to 450,000, and well above the 50,000 platelet count threshold set forth in the QAI's definition of ITP." Resp't's Report at 10; ECF No. 35 at 1–2. Citing *Wright*, Respondent argues that "ongoing testing showing normal platelet levels does not establish that H.V.L. suffered residual effects of the alleged vaccine injury for more than six months after administration of the vaccine." ECF No. 35 at 2. Respondent notes that he "cannot speculate as to whether *any* medical provider would diagnose ITP based on a platelet count of 149,000." ECF No. 40 at 1. However, he argues that the QAI, "along with the medical literature and relevant case law, strongly support [his] position that H.V.L.'s February 4, 2019 platelet count of 149,000[] . . . does not satisfy that Act's severity requirement." *Id.*

V. Discussion

H.V.L. received the vaccines at issue on September 10, 2018. Thus, in order to fulfill the severity requirement, Petitioner must establish by preponderant evidence that the residual effects or complications of H.V.L.'s injury lasted until at least March 10, 2019. *See* § 300aa–11(c)(1)(D)(i).[22] However, Petitioner has failed to present preponderant evidence that (1) H.V.L.'s ITP or (2) residual effects or complications of H.V.L.'s ITP lasted through this date.

[22] The statute's six-month requirement is unclear regarding whether the injury must last for six months following the vaccination date or for six months following the injury onset date. Although the precise onset date of H.V.L.'s ITP is unclear, H.V.L.'s parents reported increased bruising beginning the weekend before October 1, 2018, which was a Monday. *See* Pet'r's Ex. 2 at 71. This indicates that his ITP began sometime in late September of 2018. Thus, if Petitioner were required to establish that H.V.L.'s injury lasted for six months after injury onset, he would need to establish that H.V.L.'s injury lasted through late March of 2019. Because the statute is unclear, I will analyze whether Petitioner has fulfilled the six-month requirement in the light most favorable to Petitioner. I will thus determine whether he has provided preponderant evidence that H.V.L.'s injury lasted for six months post vaccinations, until at least March 10, 2019.

A. Duration of Injury

Respondent argues that H.V.L.'s ITP resolved by at least February 4, 2019, less than five months post vaccinations, when his platelet count reached 149,000. Respondent has provided persuasive evidence that a platelet count of 149,000 is inconsistent with the medical community's current definition of ITP. Respondent filed two older papers, a 1996 paper by George et al., who did not address a platelet count threshold but mentioned the importance of normal laboratory values, and a 2003 paper by Kühne et al., who defined acute ITP as "a duration of thrombocytopenia (<150 x 10^9/L) of [less than six] months." Resp't's Ex. D at 7; Resp't's Ex. E at 1. However, the 2009 Rodeghiero et al. paper noted that the IWG considered "the more commonly used level of less than 150 x 10^9/L[]" but ultimately determined "[a] platelet count [of] less than 100 x 10^9/L . . . as the threshold for diagnosis." Resp't's Ex. A at 2. Additionally, the two more recent papers Respondent filed provide criteria consistent with the IWG's recommendation. Nomura noted in 2016 that "[a] platelet count in peripheral blood of <100 x 10^9/L is the most important criterion" for ITP diagnosis, and the 2021 Cooper et al. paper defined "[p]rimary [ITP as] an autoimmune disorder characterized by reduced platelet counts (< 100 x 10^9/L) . . . ." Resp't's Ex. B at 1; Resp't's Ex. C at 2. Nomura and Cooper et al. did not discuss this criterion as a continuing topic of debate in the medical community. The medical literature, when read together, provides preponderant evidence that the medical community's conception of ITP shifted after the IWG's recommendations. Indeed, the Federal Circuit noted in the 2022 *Wright* decision that, presently, "[t]he International Working Group on ITP uses a platelet count of less than or equal to 100,000/mm^3 for diagnosis." *Wright*, 22 F.4th at 1008 n.2 (internal citations omitted). Furthermore, the QAIs state that thrombocytopenic purpura "is defined by the presence of clinical manifestations, such as petechiae, significant bruising, or spontaneous bleeding, and by a serum platelet count less than 50,000/mm^3." 42 C.F.R. 100.3(c)(7). Because Petitioner has alleged an off-Table injury as an alternative to a Table injury, he does not need to establish that H.V.L.'s ITP was consistent with the Table's definition. However, the Table's definition adds credence to Respondent's contention that a platelet count of 149,000 is inconsistent with ITP.

I have considered the letters submitted by Drs. Farber and Kaicker. However, I must consider the letters in light of the entire record. Drs. Farber and Kaicker indicated that H.V.L.'s platelet testing was not "normal" until his platelets reached 150,000 on April 1, 2019. However, Dr. Kaicker, H.V.L.'s hematologist, last saw H.V.L. in October of 2018, and she recommended only "monitoring and watchful waiting." Pet'r's Ex. 4 at 7. She did not see the need for follow-up or further treatment. *See id.* Furthermore, despite Petitioner's request that Dr. Kaicker describe H.V.L.'s ITP as unresolved until his platelets "objectively normalized," Dr. Kaicker did not comment on whether H.V.L.'s platelet count of 149,000 in February of 2019 was indicative of continuing ITP. *See* Pet'r's Ex. 9 at 40; Pet'r's Ex. 10.

Dr. Farber, H.V.L.'s pediatrician, more specifically linked the resolution of H.V.L.'s condition to a "normal" platelet count of 150,000. *See* Pet'r's Ex. 8 (noting that H.V.L. was on restricted physical activity "[u]ntil his condition resolved and his platelet counts were objectively normal[]"). However, Dr. Farber is a pediatrician, and the extent of her familiarity with hematologic disorders, and medical literature on such disorders, is unclear. Indeed, Dr. Farber presumed that H.V.L. was suffering from thrombocytopenia in October of 2018, but she referred

him to a hospital where he was formally diagnosed by a pediatric hematologist-oncologist. *See* Pet'r's Ex. 2 at 72; Pet'r's Ex. 9 at 23. Of note, in December of 2018, Dr. Farber noted that H.V.L.'s vaccinations were paused due to an acute illness listed as ITP. Pet'r's Ex. 2 at 78. At that time, H.V.L.'s platelet count was under 100,000 at 94,000. Pet'r's Ex. 3 at 44. H.V.L.'s platelets rose to 118,000, above the IWG's 100,000 recommendation threshold, by January 3, 2019. *Id.* at 47. A later record from Dr. Farber, dated March 11, 2019, no longer listed ITP under diagnosis and clinical assessment. *See* Pet'r's Ex. 2 at 90. He was then vaccinated on March 25, 2019, after recovering from croup. *See id.* at 93–94.

While the opinions of treating physicians are entitled to some weight, special masters are not required to accept a treating physician's conclusions. Indeed, the Federal Circuit has clearly stated that special masters, as finders of fact, "are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence." *Moberly*, 592 F.3d at 1326. When determining the reliability of medical or expert opinions, special masters may consider whether the issues opined on are within a witness's area of expertise. *See Wyatt v. Sec' of Health & Hum. Servs.*, 825 Fed. Appx. 880, 886 (Fed. Cir. 2020) (holding that "the factual findings of the Special Master regarding GBS [were] not arbitrary and capricious[]" when, among other issues, "the Special Master determined that Dr. DeMio's expert testimony should be given little weight because Dr. DeMio has no specialized training in autoimmune or neurological disorders and had conducted no research in either field[]"). In this case, there is no indication that Dr. Farber has specialized training in this area, and her opinion that H.V.L.'s ITP was unresolved until his platelets reached 150,000 is inconsistent with the other, more persuasive evidence.

Furthermore, even if Petitioner had provided preponderant evidence that H.V.L.'s ITP was unresolved until his platelet count reached 150,000, Petitioner has still failed to present preponderant evidence that his platelet count did not reach 150,000 until March 10, 2019, or later. Petitioner filed a status report stating that he filed all of H.V.L.'s laboratory results. ECF No. 33 at 1–3. However, while the filed records indicate that H.V.L. received one CBC per month in December of 2018 through February of 2019, it is unclear why H.V.L.'s platelets do not appear to have been tested between February 4, 2019, and April 1, 2019. *See* Pet'r's Ex. 3 at 44–50. This is especially curious in light of Dr. Farber's statement that H.V.L.'s "platelet tests were serially ordered and actively monitored in response to the fact that his platelet counts had not resolved." Pet'r's Ex. 8 at 1. H.V.L.'s CBC results indicate that his platelets were continually normalizing following his October 2018 hospitalization and IVIG treatment, even without additional treatment. This is also consistent with H.V.L.'s parents' assertion during his February 28, 2019 medical visit that H.V.L.'s "recent platelet count [was] close to 200,000." *See* Pet'r's Ex. 2 at 84. His platelet count increased from 45,000 to 79,000 between November 5 and November 26, 2018. *Id.* at 42–43. His platelets increased again to 94,000 by December 10, 2018, and they reached 118,000 by January 3, 2019. *Id.* at 44, 47. His platelet count then increased by another 31,000, to 149,000, by February 4, 2019. *Id.* at 48. This trajectory, coupled with the lack of other symptoms, does not present preponderant evidence that H.V.L. continued to suffer from ITP for an additional two months, when his platelets were measured again and found to be "normalized."

There is also clinical evidence in the medical records suggesting that H.V.L. had a sufficient platelet count before March 10, 2019. During his February 28, 2019 pediatric visit,

H.V.L. presented with an ulceration in and a bruise on his left cheek, and his parents reported that he "fell and likely bit inside of mouth[.]" Pet'r's Ex. 2 at 84. They told Dr. Farber that they "saw a great deal of blood, but bleeding stopped quickly- within [five minutes]." *Id.* Platelets are "chiefly known for [their] role in blood coagulation[.]" *Dorland's* at 1437. That H.V.L.'s bleeding "stopped quickly" suggests that his blood successfully coagulated. The medical record from this visit does not indicate that Dr. Farber was concerned about excessive bleeding, and she did not observe additional bruising or bleeding besides that related to his mouth injury. *See* Pet'r's Ex. 2 at 84–85. H.V.L. also had a bruise on his left cheek on March 11, 2019, but neither Dr. Farber nor Petitioner has asserted that this bruise was related to ITP. *See id.* at 88–90. I find that Petitioner has not provided preponderant evidence that H.V.L.'s allegedly vaccine-caused ITP continued for six months following his vaccinations.

B. Residual Effects

Although Petitioner has not presented preponderant evidence that H.V.L.'s ITP lasted for six months, he could still fulfill the Act's severity requirement by establishing by preponderant evidence that the residual effects or complications of H.V.L.'s ITP lasted for at least six months post vaccinations. Petitioner argues alternatively that the residual effects of H.V.L.'s ITP lasted for more than six months post vaccinations, but he has not specified in his pleadings what these "residual effects" were, outside of discussing H.V.L.'s platelet counts and citing Dr. Farber's letter. *See* ECF No. 15 at 1–2; ECF No. 41 at 1. The medical records do not indicate that H.V.L. experienced symptoms that were attributed to his ITP after 2018, but Dr. Farber asserted in her letter that "[she] placed [H.V.L.] on restricted physical activity[]" and that "[t]hese restrictions were not lifted until April 1, 20[19]." Pet'r's Ex. 8 at 1. However, I find that Petitioner has failed to present preponderant evidence that H.V.L suffered from residual effects or complications of his ITP for at least six months post vaccinations.

In *Wright*, the Federal Circuit explained that residual effects "[r]equire a *change within the patient* that is caused by the vaccine injury." *Wright*, 22 F.4th at 1004 (emphasis added). It determined that, in that petitioner's case, continuing monitoring was not a residual effect, because it did not cause a health detriment, and because there were no lingering symptoms or recurrence. *Id.* at 1005–06. The Circuit noted that the ongoing monitoring was "neither an 'ongoing disability' nor indicative that he 'suffered' or was 'seriously injured' within Congress's intended meaning of the severity requirement." *Id.* at 1007. In the present case, Petitioner has failed to present preponderant evidence that the activity restrictions caused a "change" within H.V.L. The medical records and physician letters contain limited information on these restrictions. Although Dr. Farber wrote that she placed H.V.L. on restricted activity and then lifted the restrictions after April 1, 2019, the medical records from her practice do not mention activity restrictions or what they were and do not indicate that she lifted activity restrictions at any point. *See generally* Pet'r's Ex. 2. Instead, activity restrictions are mentioned in records from Dr. Kaicker. On October 5, 2018, soon after H.V.L.'s ITP onset, Dr. Kaicker advised H.V.L.'s parents that he should avoid NSAIDS, head trauma, and additional vaccines. Pet'r's Ex. 4 at 21. On October 16, 2018, Dr. Kaicker provided "anticipatory guidance" that included avoidance of aspirin, NSAIDS, intramuscular injections, and "rough play[,]" as well as delay of MMR and MMRV vaccines. *Id.* at 12. Dr. Kaicker also advised H.V.L.'s parents to seek medical attention for him if he experienced certain symptoms. *Id.* However, the record does not contain evidence that any of these restrictions involved or caused a

change within H.V.L. The record does not show, and Petitioner has not contended, that H.V.L. suffered from pain, injury, or other effects from temporary avoidance of certain medications, injections, and rough play. Given that H.V.L. was between twelve and eighteen months old during the six months following his vaccinations, it is unclear what kind of play these restrictions would have prevented him from participating in.

The Federal Circuit clarified in *Wright* that its holding "do[es] not disturb existing case law holding that a course of treatment lasting longer than six months can be a 'residual effect.'" *Wright*, 22 F.4th at 1007. The Circuit cited *H.S.*, a case involving physical activity restrictions that were necessary to prevent injury aggravation, as a case its holding was not disturbing. However, because the Federal Circuit did not rule on the issue of when activity restrictions are "residual effects," I still must determine whether the purported restrictions in this case constitute residual effects lasting for six months pursuant to the Circuit's definition. Not only does the record in this case fail to show preponderant evidence that activity restrictions caused a change within H.V.L., but this case is also distinguishable from cases such as *H.S.* In *H.S.*, a child had to abstain from gym class, recess, and sports following the removal of an immobilizing brace because his "doctors were concerned about the presence of his skull fracture long after he stopped being symptomatic." *H.S.*, 2015 WL 1588366, at *1, *3. The particular restrictions prevented the child from engaging in normal activity as part of "a long course of treatment[in which] the patient [had] some lingering condition such that symptoms w[ould] likely recur if the treatment were stopped." *See Wright*, 22 F.4th at 1007. In the present case, however, there is no indication that activity restrictions changed H.V.L.'s activities or that they were necessary to prevent aggravation of an underlying injury for six months post vaccinations. For instance, although Dr. Kaicker advised that H.V.L. should abstain from intramuscular injections and vaccinations in October of 2018, within one month of H.V.L.'s ITP onset, Dr. Farber wrote that H.V.L. was "cleared for inactivated non-live vaccines[]" as of January 2, 2019. Pet'r's Ex. 4 at 12, 21; Pet'r's Ex. 2 at 78. He received Pentacel and Prevnar vaccines on January 2, 2019, and he received a hepatitis A vaccine on March 25, 2019. Pet'r's Ex. 2 at 81, 93–94.

Furthermore, the record does not contain preponderant evidence that other restrictions, such as play restrictions, were in place for six months. The medical records do not indicate when or if Dr. Kaicker or Dr. Farber lifted activity restrictions. Although Dr. Farber wrote in her letter that "restrictions were not lifted until April 1, 2020 [sic]," the medical records do not indicate that this occurred. Petitioner has not provided medical records indicating that he received instructions from Dr. Kaicker or had an appointment with Dr. Kaicker after October 25, 2018. Petitioner asked Dr. Kaicker to note that activity restrictions were not lifted until H.V.L.'s platelets "objectively normalized[,]" but Dr. Kaicker did not include this or otherwise discuss activity restrictions in her letter. *See* Pet'r's Ex. 9 at 40; Pet'r's Ex. 10. The medical records provided from Dr. Farber's office do not show communication or an appointment regarding H.V.L.'s April 1, 2019 CBC or ITP during or after April of 2019. In fact, H.V.L. presented to Dr. Farber's office for an upper respiratory infection on April 20, 2019, but H.V.L.'s ITP and CBC are not mentioned in that record. *See* Pet'r's Ex. 2 at 97–98. It is possible that Petitioner discussed activity restrictions, and the lifting of said restrictions, with Dr. Farber but that these discussions were not included in the medical records. *See LaLonde v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203–-04 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014) (stating that a medical professional's failure to document everything is a possible explanation for inconsistencies between contemporaneously created

medical records and later testimony). There is no presumption that medical records are accurate and complete. *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). However, where there are inconsistencies, special masters are within their discretion to award contemporaneous medical records greater weight than later conflicting testimony. *See Cucuras*, 993 F.2d at 1528 (holding that the special master's reliance on contemporaneous medical records over conflicting oral testimony given after the fact was not arbitrary or capricious); *see also Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that the decision of whether to accord greater weight to contemporaneous medical records or later given testimony is "uniquely within the purview of the special master"). In this case, I find that the overall record fails to show preponderant evidence that activity restrictions were in place for six months post vaccinations. Because the submitted medical records, particularly from Dr. Farber's office, do not discuss ending activity restrictions, it is unclear what documents Dr. Farber relied on, or if she relied on her memory, to discuss this in her letter. Although the record does not indicate that Petitioner sent a sample letter to Dr. Farber, Dr. Farber's letter includes phrasing similar to the sample letter Petitioner sent to Dr. Kaicker. Like Petitioner's sample letter, Dr. Farber's letter incorrectly referred to April 1, 2019, as April 1, 2020. *See* Pet'r's Ex. 9 at 40; Pet'r's Ex. 8. Due to these similarities, it is unclear whether Dr. Farber relied on a similar sample letter from Petitioner to draft her letter. Because her letter is undated and was filed nearly two years after the onset of H.V.L.'s ITP, the reliability of her recollections, if they were the basis of her letter, is unclear. I therefore find that Petitioner has failed to present preponderant evidence that H.V.L. experienced residual effects of his injury that lasted for at least six months following his vaccinations.

VI. Conclusion

After a careful review of the record, Petitioner has failed to prove by preponderant evidence that H.V.L.'s injury lasted for six months after his September 10, 2018 vaccinations pursuant to the Vaccine Act's severity requirement. Accordingly, I **DENY** Petitioner's claim and **DISMISS** his petition.[23]

IT IS SO ORDERED.

s/Herbrina D. Sanders
Herbrina D. Sanders
Special Master

[23] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of a notice renouncing the right to seek review.